

CIRM Board Approves Funding for Clinical Trials Targeting Epilepsy and Dysphagia

Posted: May 26, 2022

South San Francisco, CA – It's estimated that every year more than 65,000 Americans will be treated for head and neck cancer. One devastating and debilitating side effect of the treatment is dysphagia, or difficulty swallowing. Today the governing Board of the California Institute for Regenerative Medicine (CIRM) approved investing more than \$11 million to fund a Phase 2 clinical trial testing a cell therapy for the condition. The Board also approved investing almost \$8 million to fund a Phase 1 clinical trial testing a cell therapy for treatment of a drug-resistant form of epilepsy.

The addition of these two new programs brings the number of clinical trials directly funded by CIRM to 80.

Patients with head and neck cancer often undergo surgery and/or radiation to remove the tumors. As a result, they may develop problems swallowing and this can lead to serious complications such as malnutrition, dehydration, social isolation, or a dependence on using a feeding tube. Patients may also inhale food or liquids into their lungs causing infections, pneumonia and death. The only effective therapy is a total laryngectomy where the larynx or voice box is removed, leaving the person unable to speak.

Dr. Peter Belafsky and his team at the University of California at Davis are developing a therapeutic approach using Autologous Muscle Derived Progenitor Cells (AMDC), cells derived from a biopsy of the patient's own muscle, elsewhere in the body. Those AMDCs are injected into the tongue of the patient, where they fuse with existing muscle fibers to increase tongue strength and ability to swallow.

"Dysphagia is not only a serious problem for people recovering from head and neck cancer, it's also a problem for millions of older Americans," says Dr. Maria T. Millan, President and CEO of CIRM. "This approach has the potential to make life better for millions of Californians who are experiencing swallowing disorders but have no effective treatment options."

The CIRM Board also approved almost \$8 million for Neurona Therapeutics, to test a new approach for treating people with a drug-resistant form of epilepsy called mesial temporal lobe epilepsy (MTLE). It's one of the most common forms of epilepsy. Epileptic seizures are debilitating and increase the risk of a decreased quality of life, depression, anxiety and memory impairment.

The current therapies for drug-resistant epilepsy are only partially effective and have serious drawbacks. One treatment that can significantly reduce seizure frequency is the removal of the affected part of the brain using surgical or laser ablation methods. However, not surprisingly, removal of brain tissue can cause serious, irreversible damage, such as effects on memory, mood and vision.

Neurona has developed a therapy called NRTX-1001, consisting of a specialized type of neuronal cell derived from embryonic stem cells. These cells are injected into the brain in the area affected by the seizures where they release a neurotransmitter or chemical messenger that will block the signals in the brain causing the epileptic seizures. Pre-clinical testing suggests a single dose of NRTX-1001 may have a long-lasting ability to suppress seizures.

About CIRM

At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission.

To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies.

With \$5.5 billion in funding and more than 150 active stem cell programs in our portfolio, CIRM is one of the world's largest institutions dedicated to helping people by bringing the future of cellular medicine closer to reality.

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